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08/731,499

APPLICATION NUMBER	FILED DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/731,499	06/10/98		023070-00001

MM21/0609
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EXAMINER

UNGAR, S

ART UNIT PAPER NUMBER

1642 17

DATE MAILED: 06/09/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on March 30, 1998
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-44 is/are pending in the application.
- Of the above, claim(s) 2-17 + 21-44 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 18 + 19 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7 + 9
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit:

1. The Election filed March 30, 1998 (Paper No. 16) in response to the Office Action of February 17, 1998 (Paper No. 14) is acknowledged and has been entered. Claims 1-44 are pending in the application and Claims 2-17 and 20-44 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 1, 18 and 19 are currently under prosecution.

2. Applicant's election with traverse of Group I, claims 1-23 in Paper No 16 and the election of the species of claims 1, 18 and 19 is acknowledged. The traversal is on the ground(s) that the examination of all groups would not impose a serious burden on the examiner. The argument has been noted but has not been found persuasive because the literature search, particularly relevant in this art, is not coextensive and different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Drawings

3. The drawings are objected to because of the following informalities:

Each Figure of the drawings must be individually numbered, for example, Figure 1 has 2 panels. These must be renumbered Figure 1A, Figure 1B. Furthermore the Brief Description of the Drawings and all references to the drawings in the specification must be amended to reflect the new numbering of the drawings.

Claim Rejections - 35 USC § 112

Art Unit:

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

5. The specification is further objected to under 35 USC 112, first paragraph, and Claims 1, 18 and 19 are rejected under 35 USC 112 first paragraph as failing to provide sufficient guidance to enable one skilled in the art to use an isolated nucleic acid which hybridizes under stringent conditions to SEQ ID NO. 10.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

(A) The claims are drawn to any isolated nucleic acid molecule which specifically hybridizes under stringent conditions to SEQ ID NO. 10. This includes a plurality of nucleic acid molecules with a variety of sizes, structures, functions and origins. The specification teaches that the invention pertains to the identification of genes in a region at about 20q13 and further teaches that the sequences disclosed herein can be used as probes specific for the 20q13 amplicon as well as for the treatment of various cancers (p. 1, lines 11-14) and further states that the identification of amplified and deleted regions is crucial both for the study of tumorigenesis and for the development of cancer diagnostics (p. 1, lines 23-25) and exemplifies prognostic implications of amplification of chromosomal region 20q13 (

Art Unit:

page 44- 52). One cannot extrapolate the teaching of the specification to the scope of the claims because as broadly written the claims read on any nucleic acid molecule that specifically hybridizes under stringent conditions to SEQ ID NO. 10, regardless of size, structure or function. For example SEQ ID NO. 10 could hybridize with 30, 40 or 100 consecutive residues of a nucleic acid molecule which could be totally unrelated to the 20q13 amplicon. The specification has not taught how to use nucleic acid molecules not related to the 20q13 amplicon. Further, the specification has not taught the range of nucleotides within SEQ ID NO.10 that must be hybridized to the nucleic acid molecule in order to pick up sequences that are related to the 20q13 amplicon but will not cross react with unrelated genes. Thus, undue experimentation would be required for one skilled in the art to practice the invention as claimed.

(B) The claims are drawn to hybridization under stringent conditions to SEQ ID No. 10. This includes hybridization to a myriad of nucleic acid molecules immobilized on solid supports as well as hybridization of a myriad of nucleic acid molecules with a variety of mismatch distributions. The specification teaches, on page 6 that stringent conditions are selected to be about 5 degrees C below the T_m for the specific sequence at a defined ionic strength and pH. However, one cannot extrapolate the teachings of the specification to the scope of the claims because Sambrook et al (Molecular Cloning, 2nd Ed, Cold Spring Harbor Laboratories, Cold Spring Harbor, 1989, pages 9.47-11.57) clearly teach that the kinetics of hybridization reactions are difficult to predict from theoretical considerations (such as T_m) partly because the exact concentration of an immobilized nucleic acid and its

Art Unit:

availability for hybridization are unknown (see sentence bridging pages 9.47-9.48). Further, Sambrook et al teach that the precise effect of mismatches on the T_m depends not only on the G+ C content of the nucleotide but even more critically on the distribution of mismatches bases. Mismatches in the middle of the nucleotide are far more deleterious than mismatches at the ends. Therefore a method of hybridization conditions, based on T_m , should only be used as a rough guide until a systematic study of all types of mismatches in a variety of contexts leads to more precise methods of estimation (page 11.46-11.47). Clearly, the disclosure does not provide guidance on or exemplification of stringent hybridization conditions for the broadly claimed invention. In view of the above, one skilled in the art would be forced into undue experimentation to practice the invention as claimed.

6. The specification is further objected to under 35 USC 112, first paragraph, and Claim 19 is rejected under 35 USC 112 first paragraph as failing to provide sufficient guidance to enable one skilled in the art to make/use an isolated nucleic acid which hybridizes under stringent conditions to SEQ ID NO: 10 wherein the sequence is SEQ ID NO. 10.

The claim is drawn to the hybridization of SEQ ID NO: 10 to SEQ ID NO: 10. The specification teaches that hybridizing refers to the binding of two single stranded nucleic acids via complementary base pairing (page 6, lines 1-2). One cannot extrapolate the teaching of the specification to the claim because the specification does not teach how to hybridize two identical single stranded nucleic acids and it is clear that Seq ID No. 10 is identical to and not the complement of

Art Unit:

SEQ ID NO. 10. Thus, one of skill in the art would be forced into undue experimentation to practice the invention as claimed.

7. Claim 1, 18 and 19 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 18 and 19 are confusing because claim 1 recites the term "subsequence". The claims are indefinite because the term is not defined in either the claims or the specification, thus it is not possible to ascertain the size of the hybridizing subsequence or its position on the isolated nucleic acid molecule and the metes and bound of the claimed patent protection cannot be determined.

Claim 19 is confusing because it is not clear what is meant by hybridizing Seq ID No. 10 to Seq ID No. 10.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 1 and 18 are rejected under 35 U.S.C. § 102(a) as being anticipated by Genbank-Est106 accession no. W05407, NID g1278138, publicly available April 23, 1996.

Art Unit:

The claims are drawn to an isolated nucleic acid sequence comprising a polynucleotide sequence having a subsequence which specifically hybridizes under stringent conditions to a sequence selected from the group including SEQ ID NO. 10.

Accession No. W05407 teaches a nucleic acid cDNA clone which has 473 base pairs, one strand of which is 96.9% identical to 13.2% of SEQ ID NO. 10, the complementary strand of which will specifically hybridize to SEQ ID NO. 10 under stringent conditions.

10. No claims allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached at (703) 308-2731. The fax phone number for this Art Unit is (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 USC 132 or which otherwise require a signature may be used by the applicant and should be addressed to lila.feisee@uspto.gov.

All internet e-mail communications will be made of record in the application file. **PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the**

Art Unit:

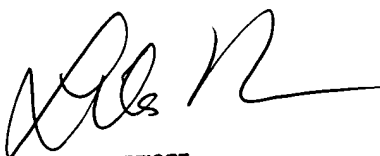
confidentiality requirements of USC 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar

June 1, 1998



LILA FEISEE
SUPERVISORY PATENT EXAMINER